UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., *Plaintiff*, v. BIONPHARMA INC., *Defendant*.	C.A. No. 21-1286-LPS

DEFENDANT BIONPHARMA'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR EXTENSION OF TIME

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Defendant Bionpharma Inc. ("Bionpharma") respectfully submits the instant Reply Brief in support of its Motion for Extension of Time for the parties to submit a proposed scheduling order (D.I.[1] 99) ("Bionpharma's Motion").

REPLY ARGUMENT

Bionpharma respectfully submits that Plaintiff Azurity Pharmaceuticals, Inc.'s ("Azurity") arguments against extension in its Opposition (D.I. 102) are meritless and reinforce that an extension of time for the parties to submit a joint proposed scheduling order is warranted.

I. AZURITY BEARS FULL RESPONSIBILITY FOR ANY DELAY IN RESOLUTION OF THIS CASE

Azurity complains of delay. D.I. 102, Azurity's Opp'n at 1-2. But any delay in resolution of this case was self-inflicted by Azurity, who, having lost the First Wave Suits[2] and the Second Wave Suit[3] in this Court, originally filed the instant suit in the District of New Jersey (D.I. 1, Compl.) in order to get away from this Court's adverse rulings, and vigorously opposed a § 1404(a) motion Bionpharma filed (D.I. 7) to transfer this case back here, going so far as to ***falsely argue to the New Jersey court that the instant action was not related*** to the First and Second Wave Suits, or to any of the other enalapril liquid patent litigations that are currently pending in this Court. D.I. 31, Azurity's Opp'n to Def.'s Mot. to Transfer at 3-6. However, after the New Jersey court granted Bionpharma's § 1404(a) motion and transferred the instant case here (D.I. 57), Azurity filed a letter with Your Honor's Clerk's Office ***finally admitting that the instant action***

[1] All "D.I." citations are to the docket for the instant 21-1286 action unless otherwise specified.

[2] *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962-LPS, 19-1067-LPS (D. Del.).

[3] *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 20-1256-LPS (D. Del.).

was in fact related to the First and Second Wave Suits and the other pending enalapril liquid patent litigations. D.I. 63, Sept. 14, 2021 Ltr. from M. Dellinger to J. Cerino, Clerk of the Court.

Next, in late October 2021—three years after Azurity began suing Bionpharma for alleged infringement of its enalapril liquid patent family—Azurity for the first time sued Bionpharma's contract manufacturer, CoreRx, Inc. ("CoreRx"), in this Court and in the Middle District of Florida, and then voluntarily dismissed both suits a month later.[4,5] As explained in Bionpharma's Opening Brief in Support of its Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6), Azurity's voluntary dismissal of the Delaware and Florida CoreRx suits has provided Bionpharma with yet another claim preclusion defense that Bionpharma is entitled to raise as a motion to dismiss. D.I. 98, Bionpharma's MTD Br. at 7-13; *Toscano v. Conn. Gen. Life Ins. Co.*, 288 F. App'x 36, at 38 (3d Cir. 2008) ("The defense of claim preclusion, . . . , may be raised and adjudicated on a motion to dismiss."). As Bionpharma has lawfully filed a colorable motion to dismiss, Bionpharma is not obligated to answer the First Amended and Supplemental Complaint (D.I. 89, "First Amended

[4] D.I. 98-1, Bionpharma's Br. in Support of its Mot. to Dismiss ("Bionpharma's MTD Br.") Ex. A, *Azurity Pharm., Inc. v. CoreRx, Inc.*, No. 8:21-cv-2515 (M.D. Fla.) ("Florida CoreRx suit"), D.I. 1, Compl. (without attachments); *Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-LPS (D. Del.) ("Delaware CoreRx suit"), D.I. 1, Compl.; D.I. 98-2, Bionpharma's MTD Br. Ex. B, Florida CoreRx suit, D.I. 16, Notice of Dismissal without Prejudice; Delaware CoreRx suit, D.I. 6, Notice of Dismissal without Prejudice.

[5] As explained in Bionpharma's December 13, 2021 Letter to the Court (D.I. 103), the Delaware and Florida CoreRx suits were never about enforcing legitimate patent rights, as the private equity firm that owns Azurity—NovaQuest Capital Management ("NovaQuest")—acquired CoreRx earlier this year. D.I. 103, Dec. 13, 2021 Bionpharma Ltr. to the Court Ex. B, Bionpharma's Fla. Mot to Intervene at Exs. B-D. Instead, those suits represent sham litigation and a misuse of the Federal courts, as Azurity and CoreRx are commonly-owned affiliates, and there was never any justiciable case or controversy between adverse litigants sufficient to support subject matter jurisdiction over Azurity's patent infringement claims against CoreRx in either of the Delaware and Florida CoreRx suits. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

Complaint") until two weeks after Bionpharma's Motion to Dismiss is denied (or postponed). FED R. CIV. P. 12(a)(4).

Thus, Azurity's blatant forum shopping, false and conflicting arguments about the nature of this case, and sham litigation against its sister company (CoreRx), are what have led to any "delay" in resolving the instant matter, and Bionpharma should not be penalized for Azurity's improper conduct that has led to any delay.

II. THE PARTIES AND COURT STILL DO NOT KNOW WHAT THE FULL SCOPE OF THIS CASE WILL BE

As Bionpharma has not yet answered the First Amended Complaint, the parties still do not know what the full scope of this case will be; thus, submission of a proposed schedule is entirely premature. As explained in Bionpharma's December 8, 2021 letter to the Court responding to Azurity's submission of a proposed scheduling order (D.I. 101), because of certain anticompetitive activity Azurity has engaged in with respect to Bionpharma's ANDA,[6] Bionpharma may be filing antitrust counterclaims against Azurity. Azurity's only response to this is that "[t]his case should not be held hostage by Bionpharma's potential, yet unasserted, claims and defense and unilateral delay in filing its answer." D.I. 102, Azurity's Opp'n at 3. This response from Azurity ignores the fact that—as outlined above—Azurity is to blame for any delay in the filing of Bionpharma's answer or resolution of this case. Importantly, Azurity does not dispute that, if Bionpharma does bring antitrust claims, the abbreviated schedule it has proposed to the Court would be inadequate. *See generally* D.I. 102, Azurity's Opp'n. The parties should be allowed to know the full scope of

[6] Bionpharma has outlined some of this anticipative behavior from Azurity in its December 13, 2021 letter to the Court (D.I. 103 at 2-3).

the claims and defenses that will be raised in this case before being required to negotiate and submit a proposed scheduling order.

III. BIONPHARMA WILL NEED EXTENSIVE DISCOVERY

Even if the Court were to consider Azurity's proposed schedule at this time, Bionpharma respectfully submits that the schedule is inadequate and would not afford the parties sufficient time to investigate claims and defenses in this case that are or may be raised. Azurity points to a few Bionpharma discovery request responses from the First Wave Suits and argues that Bionpharma has already had discovery on invalidity. D.I. 102, Azurity's Opp'n at 2-3. This argument is belied by arguments Azurity made in opposing Bionpharma's first Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6). *See* D.I. 8 ("Bionpharma's First Motion to Dismiss"). In opposing Bionpharma's First Motion to Dismiss, Azurity vigorously argued that the claims of the patent-in-suit, U.S. Patent No. 11,040,023 B2 ("'023 patent"), were materially different than the claims of the patents that were at issue in connection with the First Wave Suits ("First Wave Patents"). *See* D.I. 48, Azurity's Br. in Opp'n to Def.'s Mot. to Dismiss at 9. Specifically, Azurity argued that "there are several differences in claim limitations, [and] the absence of a 'buffer limitation,' in particular, ***meaningfully changes the scope of the claims of the '023 Patent from that of the [First Wave Patents]***." *Id*. (emphasis added). Bionpharma has never had any fact discovery on this allegedly material aspect of the '023 patent claims, which has provided Bionpharma with written description and non-enablement defenses that this Court has found raise "substantial questions" regarding the validity of the claims of the '023 patent. D.I. 96, Nov. 10, 2021 Hr'g Tr. 103:10-108:3. Because Bionpharma has not had any fact discovery on at least the written description and non-enablement defenses it has raised, Azurity's proposal for a four month fact discovery period in this case (D.I. 100, Proposed Scheduling Order at 3) is wholly inadequate.

Next, as alluded to in Bionpharma's December 8, 2021 letter to the Court (D.I. 101), Bionpharma may have non-infringement defenses that were never available in connection with the First and Second Wave Suits. Attached hereto as Exhibit A is the November 2020 Master Manufacturing Supply Agreement between Bionpharma and CoreRx, which governs CoreRx's commercial manufacture and supply of Bionpharma's ANDA product ("MMSA").[7] Under the MMSA, CoreRx is defined as "CoreRx, Inc., . . . and its Affiliates, (collectively, "CoreRx")." Ex. A, MMSA at 1. "Affiliates," in turn, is defined to include "any party . . . under common control with such Party." *Id*. As explained in Bionpharma's December 13, 2021 letter to the Court, as of January of this year, Azurity and CoreRx are under common ownership and are sister companies. D.I. 103, Dec. 13, 2021 Bionpharma Ltr. to the Court at 3. Thus, Bionpharma very likely has a license to the patents-in-suit, and will need fact discovery in connection with this licensing defense, as well as related patent exhaustion/first sale doctrine defenses. Such discovery will include document production, written discovery, and depositions regarding Azurity's corporate structure, ownership/affiliation, and the MMSA, and likely third party discovery directed to CoreRx and NovaQuest relating to these issues.

The foregoing invalidity and non-infringement defenses were never investigated during the First and Second Wave Suits, and Azurity's attempt to foreclose Bionpharma's ability to seek discovery on these defenses by unilaterally submitting a proposed scheduling order with a woefully short discovery period should be rejected.

[7] Confidential financial terms have been omitted.

IV. AN EXTENSION WOULD ALLOW THE PARTIES TO CONFER AND PROPOSE A SCHEDULE FOR THE 21-1455-LPS SUIT

Shortly after the instant suit was transferred to this Court, Azurity filed Civil Action No. 21-1455-LPS against Bionpharma on October 15, 2021, asserting infringement of U.S. Patent No. 11,141,405 B2 ("'405 patent"). Bionpharma has also moved to dismiss the Complaint in the 21-1455 suit on claim preclusion grounds and the "two dismissal rule." *See* 21-1455 D.I. 12. The claims of the '405 patent are essentially duplicative of the claims of the '023 patent. *Compare* D.I. 89-1, First Am. Compl. Ex. A, '023 patent at claims, *with* 21-1455 D.I. 1-1, Compl. Ex. A, '405 patent at claims. Thus, it would make sense for the parties to discuss schedules for both the 21-1286 and 21-1455 actions together, and whether the cases should be consolidated or coordinated under one schedule, or whether the 21-1455 action should be stayed pending resolution of the instant 21-1286 suit. This consideration also supports an extension of the deadline for the parties to submit a proposed scheduling order for the instant suit.

V. IF THE COURT DISAGREES, BIONPHARMA RESPECTFULLY REQUESTS LEAVE TO SUBMIT A PROPOSED SCHEDULING ORDER

If the Court believes that a schedule can be set for this action before Bionpharma's Motion to Dismiss has been resolved, and before Bionpharma has answered the First Amended Complaint, Bionpharma respectfully requests leave to submit a proposed scheduling order one week from the Court's order denying the instant Motion.

CONCLUSION

For the foregoing reasons and those explained in Bionpharma's Motion (D.I. 99), Bionpharma respectfully requests that the December 7, 2021 deadline for the parties to submit a proposed scheduling order be extended until two weeks from the date the Court resolves Bionpharma's pending Motion to Dismiss (D.I. 97).

Dated: December 15, 2021

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CERTIFICATE OF SERVICE

The undersigned certifies and states that a true and accurate copy of the foregoing DEFENDANT BIONPHARMA'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR EXTENSION OF TIME was served on the counsel for Plaintiff by electronic mail on December 15, 2021, to:

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